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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,845	01/13/2000	DAVID A. ESTELL	GC382-US	5579

7590

01/03/2002

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EXAMINER

PAK, YONG D

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,845

Applicant(s)

ESTELL, DAVID A.

Examiner

Yong Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9-11 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-11 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The amendment filed on December 18, 2001, canceling claims 8 and 12-16, has been entered. This application is a 371 of PCT/FI99/00410.

Claims 1-7, 9-11 and 16-20 are pending.

Election/Restrictions

Applicant's election with traverse of Group II in Paper No. 8 is acknowledged. The traversal is on the ground(s) that examinations of the entire groups of claims do not require an undue burden on the examiner. This is not found persuasive because due to the recognized divergent subject matter between Inventions I-X and their different classification of Class and subclass, an unduly extensive and burdensome search is required for Inventions II-X that is not required for Invention I.

Claim 20 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Drawings

Drawings filed concurrently with the application have been approved by the Draftsman.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When

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claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 17-21 have been renumbered as claims 16-20.

Claim 10 is objected to because of the following informalities: Claim 10 is missing a period. Appropriate correction is required.

In claim 3, the genus species names should be italicized.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 9-11 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-7, 9-11 and 16-19 are drawn to a microorganism comprising a mutated gene encoding SP1 or serine protease 1 and a method of using said microorganism. Therefore, these claims are drawn to a genus of serine protease 1 genes, with any structure and from any source. The specification teaches one representative species, serine protease 1 from *Bacillus subtilis* of SEQ ID NO:1. One representative species is

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not enough to describe the whole genus and there is no evidence on the record of the relationship between the structure of a *B. subtilis* serine protease 1 and the structure of a serine protease 1 from another source. Therefore, the specification fails to describe other representative species of the genus of serine protease 1 genes.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claim 1-7, 9-11 and 16-19.

Claims 1-7, 9-11 and 16-19 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid encoding serine protease 1 of SEQ ID NO: 1, does not reasonably provide enablement for a serine protease 1 gene not homologous to SEQ ID NO:1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

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Despite knowledge in the art for the isolation of amino acids, the specification fails to provide guidance regarding how to isolate other serine protease 1 gene whose sequence is not homologous to SEQ ID NO:1. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

The predictability as to the level of conservation between the disclosed sequences and those of other serine protease 1 is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

Therefore, one of ordinary skill would require guidance in order to make serine protease 1 gene not homologous to SEQ ID NO:1 in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 and 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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In claims 1-7 and 9-10, the mere recitation of the name "SP1" is insufficient to convey with clarity that which applicant sees as the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9-10 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Band et al.

Band et al. (form PTO-892) teach a *Bacillus subtilis* having a mutated gene encoding a serine protease-1 resulting in the inactivation of the proteolytic activity (abstract, page 444, 2nd column). *Bacillus subtilis* is capable of expressing heterologous enzymes such as lipases (see Power et al. U.S. Patent No. 5,429,950). Band et al. also teach an expression vector comprising the gene encoding serine protease-1 and a host cell comprising said expression vector (page 444, 2nd column). Therefore, the teachings of Band et al. anticipates claims 1-7, 9-10 and 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11, 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Band et al. in view of Sloma et al. and Power et al.

Band et al. teach a *Bacillus subtilis* having a mutation of the gene encoding a serine protease-1 resulting in the inactivation of the proteolytic activity, as discussed above.

The difference between the reference of Band et al. and the instant invention is that Band et al. do not teach a microorganisms comprising a mutated serine protease 1 gene further comprising a mutated epr gene nor a method of producing a heterologous protein using said microorganism.

Sloma et al. (form PTO-892) teach a *Bacillus subtilis* comprising a mutated epr gene (abstract page 5557, Materials & Methods page 5557 and Results page 5557).

Power et al. (U.S. Patent No. 5,429,950) teach a method of producing heterologous proteins, such as a lipase, in *Bacillus* (Column 4, line 45 through Column 8, line 65 and Claims 1-24).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to make a *Bacillus subtilis* comprising a mutated serine protease-1 gene and a mutated epr gene and to use the microorganism in production and secretion heterologous lipases without proteolytic degradation. The motivation of using such a host system with the mutate proteases is to decrease

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proteolytic activity during the production and secretion of the heterologous protein. One of ordinary skill in the art would have had a reasonable expectation of success since recombinant production of heterologous proteins in *Bacillus* is routinely performed in the art.


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 703-308-9363. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is 703-746-3173.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Yong Pak
Patent Examiner


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December 27, 2001